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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,384	10/20/2003	Curtis Wright IV	6750-237-99	2381

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,384	WRIGHT, CURTIS	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *24 and 27-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23, 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on December 6, 2007 is acknowledged. Claims 1-44 are pending in this application. Claims 24 and 27-44 remain withdrawn. Claims 1-23 and 25-26 are under prosecution.

Maintained Rejections

Claim Rejections – 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 4, 7-20, 22-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Benecke et al. (US Patent 5,008,110).

Pagedas teaches a transdermal segmented dosage unit for administering a dosage of a pharmaceutical to the skin of a patient. The dosage unit includes a backing layer which is non-permeable with respect to a pharmaceutical to be administered by the dosage unit and extends coextensively with the patch prior to removal , a membranous layer that is permeable to the pharmaceutical, a biologically acceptable adhesive, an impermeable coating means for dividing and severing the dosage unit into pre-selected segmental areas corresponding to fractional dosages of pharmaceutical. The fractional dosages may be administered in any pre-selected combination (abstract).Pagedas discloses the adhesive serves to adhere the dosage unit to the skin

of the patient recieiveing the dosage and may be over the entire surface of the porous membrane or may define an adhesive free zone (column 3, lines 20-35) Therefore, the structural limitations of claims 1, 3, 21-23, and 25-26 have been met.

Regarding claim 2, it is the position of the examiner that a skilled artisan would have the knowledge to apply the patch to any area of interested on the patients skin in order to achieve the desired treatment from the patch. Furthermore, Figure 6 shows 2 patchs being applied to the torso an individual.

Regarding claims 12-19, Pagedas's transdermal dosage unit, discloses, "a series of perforations or alternately, scoring lines, with purpose to divide the dosage unit into a series of dose specific segments. Thus the dosage unit patch may be used in its entirety for the full dosage, or in the alternative, may be separated along perforate or scored lines to reduce the dosage received by a predetermined amount" (column 1, lines 50-55). It is the examiners position that the skilled artisan would also be able to manufacture the patches in whatever size, shape, and amount of units desired. It would also be within the knowledge of the skilled artisan to package the patches in any way deemed appropriate including reseal able packages. Applicant's attention is directed to Pagedas's drawings for a clear representation of the dosage units. Applicants attention is directed to MPEP 2144.04 IV, in which the court held that changes to dimensions where the dimensions would not perform differently are not patentably distinct over the prior art. Furthermore the recitation of packaging components in which the transdermal patch are stored, do not provide a patentable distinction between the prior art patch and

the instant patch since the packaging do not change the performance characteristics and thus a material effect on the method of using/treatment.

Pagedas does not teach the pharmaceutical agent to be buprenorphine or the use of a softening agent selected from dodecanol, undecanol, octoanol, esters of carboxylic acids or combinations thereof.

Regarding claim 4, Benecke teaches a transdermal device for the topical administration of buprenorphine, a narcotic analgesic, in which the device comprises a drug reservoir that contains the drug formulation (abstract).

Regarding claim 10, Benecke further discloses the use of dodecanol and natural or synthetic rubbers such as silicone rubber, styrene-butadiene, butyl, neoprene, polybutadiene, polyisoprene, and polyurethane elastomers; vinyl polymers, such as polyvinylalcohol, polyvinyl ethers, polyvinyl pyrrolidone, and polyvinylacetate; cellulose derivatives such as ethyl cellulose, methyl cellulose, nitrocellulose, and carboxymethyl cellulose; and natural gums such as guar, acacia, karaya, pectins, starch, dextrin, albumin, gelatin, casein, etc (column 6, lines 1-24).

Regarding claim 11, Benecke further discloses the drug delivery device may comprise a skin permeation enhancer such as propylene glycol, methyl laurate, or methyl caprylate (column 4, lines 60-64).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the transdermal segmented dosage units taught by Pagedas with the agent taught by Benecke in order to provide a method of delivering buprenorphine to a patient and "if the patient is unable to tolerate the full dosage, may

use any fractional dosage obtainable by separating out the appropriate fractional dose from the total dosage patch. The fractional doses unused after separation may be used at a later time, thus reducing waste" (Pagedas, column 1, lines 61-65).

Applicant would have a reasonable expectation of success since both references teach the use of transdermal patches for administering a drug to a patient.

Regarding the limitations of claims 7-9, the instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of the drug, to prepare a composition for topical administration because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claim 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Benecke et al. (US Patent 5,008,110) and further in view of Miranda et al. (US Patent 5,091,186).

The combined teachings of Pagedas and Benecke are discussed above and applied in the same manner.

Pagedas and Benecke do not disclose the use of a rate-limiting layer disposed on the drug layer or a drug in matrix.

Miranda discloses a transdermal delivery device for administration of a drug. Miranda discloses that it may be necessary or desirable to include an element in the device that will control the release rate of the drug or enhancer and such elements are known in the art (column 4, lines 55-64). Miranda further discloses suitable materials for the drug reservoir layer include polyethylenes, polysiloxanes, polyacrylates, and polyurethanes (column 4, lines 33-42).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated a rate limiting releasing agent into the drug layer since it is commonly known in the art to be preformed to enhance the effectiveness of the delivery device.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Pagedas does not teach or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer, wherein the borders are free of any drug, as recited in amended claims 1, 25 and 26, respectively. In addition, Pagedas does not disclose or suggest a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer as recited in amended claim 1, buprenorphine as recited in amended claim 25, or a narcotic analgesic as recited in amended claim 26. The examiner disagrees with Applicants assessment of the

Pagedas reference. Pagedas discloses the adhesive serves to adhere the dosage unit to the skin and my be over the entire surface or may define an adhesive free surface (column 3, lines 20-35). Applicant's attention is drawn to the drawings which show the membrane with a border around it consisting of the backing layer. Since the drug of the dosage unit is confined to the membrane, one of ordinary skill in the art would determine that the border would comprise the adhesive material without drug admixed therein.

Applicant further argues Benecke does not teach or suggest a patch unit having a drug layer disposed on a backing layer and a portion of an adhesive layer disposed on the borders of the backing layer, as recited in the present claims. In fact, Benecke teaches away from a drug layer disposed on a backing layer, as recited in amended claims 1, 25 and 26. The drug reservoir in Benecke is not disposed on the backing layer. Instead, the drug reservoir of Benecke is encapsulated within a hermetically-sealed compartment (see, *e.g.,* Abstract; Figs. 2 and 6). Benecke discloses that such structure prevents the drug formulation from contacting adhesive (Abstract). As such, one skilled in the art would not find suggestion or motivation in Pagedas or Benecke to modify or combine the teachings of these references to obtain the presently claimed invention. It is unclear to the examiner how applicant has determined Benecke teaches away from the instant claims. Benecke discloses skin permeation enhancers used in transdermal application as well as the specific drug of the instant claims. Therefore, it is the position of the examiner that it would have been obvious to have incorporated the

permeation enhancers and drugs disclosed by Benecke, which are known to be administered transdermally, with the transdermal device of Pagedas.

Applicant has not provided any arguments regarding the combination of Miranda with Pagedas and Benecke other than stating it does not remedy the alleged deficiencies.

Newly Applied Rejections

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Benecke et al. (US Patent 5,008,110) and further in view of Katz et al. (US Patent 5,028,435).

The combined teachings of Pagedas and Benecke are discussed above and applied in the same manner.

Pagedas and Benecke do not disclose the drug being encapsulated in microcapsules.

Katz discloses a transdermal patch comprising the encapsulation of the active drug in microcapsules (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the teachings of Katz's encapsulation with the transdermal patch of Pagedas and Benecke since encapsulating the drug with a polymer blend allows for the controlled release of the drug from the device.

Conclusion

No claims are allowed. Due to the new grounds of rejection, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615